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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,162	12/16/2005	Stanley Nattel	20111-43	1989

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,162	NATTEL, STANLEY	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/1/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11,12 and 14-26* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 15-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11,12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9,11,12 and 14-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/01/09 has been entered.

2. Applicant's argument filed 6/01/09 has been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-9, 11-12 and 14-26 are pending, claims 9, 11-12 and 14 are rejected in this office action. Claims 1-2, 4-8 and15-26 are withdrawn.

5. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claim.

Applicant's statement that "[a]mended claim 9 is directed to the prevention of a first occurrence of atrial fibrillation" clarifies the record but now constitutes a rejection

under 35 U.S.C. 112, first paragraph. Therefore the rejection under 35 U.S.C. 112, first paragraph in the Office action Paper No 20080416 is reinstated.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter (prevention) which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

In summary

Nature of the invention: All of the rejected claims are drawn to a method of preventing the first occurrence of atrial fibrillation (AF)…by step administering to a mammal in need thereof an amount of a statin drug therapeutically effective for reducing the incidence of a first occurrence of AF in the mammal. The nature of the invention is extremely complex in that it encompasses the actual prevention of AF such that the subject treated with a statin does not ever have the incidence of a first occurrence (see Applicant's response in Paper No. 20090601).

Breadth of the claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass prevention of the first incidence of AF in a subject which has potentially many different causes (i.e. patients with high blood pressure, high cholesterol, coronary artery disease, heart valve disease, chronic lung disease, cardiomyopathy, congenital heart disease, pulmonary embolism, stress etc) and different combination of symptoms each of which may or may not be addressed by the administration of the statin drug for the prevention of the incidence of a first occurrence of AF.

Guidance of the specification: The guidance given by the specification as to how the claimed compounds (i.e., statin drugs) to a mammal in order to actually prevent the incidence of a first occurrence of AF is not taught.

Predictability of the art: The lack of significant guidance from the specification or prior art with regard to the actual prevention of the first occurrence of AF in a human

subject with statin drugs makes practicing the claimed invention unpredictable in terms of preventing the first occurrence of AF.

The amount of experimentation necessary: undue experimentation will be required in practicing such an invention because one skilled in the art could not envision how to prevent the incidence of a first occurrence of AF in a patient taking a statin drug because many variables are involved in prevention. For example, the patient's condition, severity, complication of other diseases etc all play a major role in prevention of such a complex disease. The skill artisan would further have to determine when preventing should start with one of the claimed compounds, which the specification fails to teach.

7. Claims 9, 11 and 14 stand rejected under 35 U.S.C. 102(a) as being anticipated by West et al. (2002) for the reasons made of record in Paper No. 20081231 and as follows.

Applicant argues [a]mended claim 9 is directed to the prevention of a first occurrence of atrial fibrillation. Applicant also argues that there is no mention or teaching in West that administering a statin can prevent a first occurrence of atrial fibrillation.

In response all that is required in the claim is the administration of an effective amount of a statin drug that reasonably reduces the first incidence of AF due to the inherent properties of the drug, simvastain. Statins inhibit an enzyme which controls the rate of cholesterol production in the body. These medications lower cholesterol by

slowing down the production of cholesterol and by increasing the liver's ability to remove the LDL cholesterol already in the blood. Patients with high blood pressure, high cholesterol are at risk of suffering from the incidence of a first occurrence of atrial fibrillation.

Specifically, West teaches that studies of the Heart Protection with simvastin showed 27% reduction in the total stroke rate and pravastatin showed a reduction of 20% (see page 2513 rt. col.). Since these conditions all lead to atrial fibrillation, once the drug is administered, it inherently will reduce the incidence of a first occurrence of atrial fibrillation in a patient, because the only active step recited is “administration”.

Careful consideration has been given to the remarks but found not persuasive.

8. Claims 9, 11-12 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over West et al. (2002) in view of Hanson (US 6,376,242) taken with Ullah et al. (US 6,235,311), for the reasons made of record in Paper No. 20081231 and as follows.

Applicant argues that neither West nor Hanson or Ullah teaches the claim limitations of instant claims 9, 11-12 and 14. Applicant also argues that “while Ullah discusses the prevention of coronary heart disease, atrial fibrillation is a problem of the heart muscle in which the atrium contracts erratically and the applicant respectfully submits, is not related to coronary heart disease, such as those discussed in Ullah”

Applicant further argues that "it would not be obvious that a substance administered to a patient after atrial fibrillation have occurred, as mentioned in West and Hanson, could have preventive effects, as claimed in claim 9".

West is applied here as above.

With regards to Hannon not teaching the claimed invention, this is found not persuasive because any set population that has administered a statin drug would reduce the incident of a first occurrence of atrial fibrillation, as claimed. Nonetheless, Hannon teaches "subjects having abnormally elevated risk of an ischemic stroke also include individuals having any cardiac condition that may lead to decreased blood flow such as atrial fibrillation".

Hanson teaches administering statins such as simvastatin to "humans" and mammals suffering from atrial fibrillation and cardiovascular disease (i.e., as it relates to claims 9 and 11). See col. 3, line 50, col. 10, lines 56-60, col. 12, line 64 and col. col. 35, lines 37-40. Hanson further teaches the drugs are administered at 0.01-30 mg/kg/day (see col. 42, lines 15-16; as it relates to claim 12). However, Hanson is silent in the teaching of reducing the incidence of AF. Therefore Ullah was introduced to show that these drugs are known in the art to reduce AF.

Ullah et al. teach administering a statin (simvastatin) to reduce the risk of or treating cardiovascular event or disease including coronary artery disease. See col. 1, lines 58-65 and col. 2, lines 48-50.

It would have been obvious to administer West's or Hanson's simvastatin in patients with high cholesterol levels before a first incidence of AF because both West and Hanson teach the use of simvastatin in patients that require lowering of cholesterol.

9. No claim is allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
7/23/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649